IMPLEMENTATION OF DIABETIC FOOT RISK ASSESSMENT (DIAFORA) SCORE TO STUDY DIABETIC FOOT AND PREDICT AMPUTATION: AN INDIAN PERSPECTIVE

Diabetology

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ABSTRACT

BACKGROUND-Diabetic foot is a wound failing to heal after 4 weeks of onset which can result from trauma, peripheral arterial disease and/or sensory neuropathy affecting the feet in diabetes mellitus. **METHODS-** With that background we aim to predict the functionality of a relatively new score called DIAFORA in the North Indian population, by studying parameters like neuropathy, presence of foot deformity, peripheral arterial disease, multiple ulcers, infection, gangrene, bone involvement along with blood sugar levels and culture results. We classified patients with diabetic foot into 3 risk groups- low risk, medium risk and high risk to predict lower limb amputation.

RESULTS-With a 41:8 male-female ratio, our study subject's mean age was 55.38+/- 11 years. Examining patients 90 days post enrollment in our study, 70% of the 30 cases in the high risk group required amputation, 40% of the 5 cases in medium risk groups underwent amputation whereas amputation was redundant in all 15 cases belonging to the low risk group. According to our study, the DIAFORA score has a sensitivity of 91.3% and specificity of 66.7%.

CONCLUSION- With a prevalence of approximately 15% diabetic foot in India, this study is a paradigm to predict the amputation in high risk patients. Along with stringent blood sugar control we recommend utilization of DIAFORA score in regular clinical practice by clinicians to predict and prevent amputation in Diabetics and hence improve their quality of life.

KEYWORDS

Diabetic Foot Ulcer, DIAFORA Score, Foot Amputation, Diabetes complication

1.INTRODUCTION

Diabetes mellitus is a chronic multisystem disorder with many dreaded complications including diabetic foot ulcers (DFU) leading to limb amputation. The global diabetes prevalence in 2019 is estimated to be 9.3% (463 million people), rising to 10.2% (578 million) by 2030 and 10.9% (700 million) by 2045.[13] The most common complication of diabetes is lower extremity diseases followed by hospitalization.[7] Around 7-10% of people with diabetes develop chronic lower limb ulcers which are a serious and expensive complication with limb or life-threatening conditions.[6] John Hopkins Diabetes Guide defines DFU as a full-thickness wound, through the dermis, below the ankle on a weight-bearing or exposed surface in an individual with diabetes.[16] American Diabetes Association defines chronic diabetic foot ulcers as a wound failing to heal after 4 weeks.[3] With 42 million diabetic patients in India, foot ulcers are the most common complication affecting approximately 15% of diabetic patients during their lifetime.[15] A simple and accurate assessment of the risk of Diabetic Foot ulcer and its complication is vital to guide our daily clinical practice and to reduce the incidences of Diabetic foot complication.

This Study was aimed to use a new system of Diabetic Foot Ulcer classification called Diabetic Foot Risk Assessment Score (DIAFORA),[11] to classify subjects with diabetic foot into three distinct classes (low, moderate and high risk groups) and to predict lower extremity amputation (LEA) after 90 days. The DIAFORA score for predicting lower extremity amputation is an internationally established score for Diabetic foot amputation and includes 8 parameters as shown in Table 1 below. This score can be used to determine the probability of amputation and the focus of management of a diabetic foot ulcer is primarily to avoid amputation of lower limb extremities. Thus, early recognition and appropriate therapy of diabetic foot complications may save the foot and leg[11]

Table 1: DIAFORA score including the 8 parameters and their score

VARIABLES	DEFINITION	POINTS
Distal Peripheral Neuropathy (DPN)	Inability to feel SMW at>1 of 4 points (hallux pulp, first, third and fifth MTT heads)	4
Foot deformity	Foot alteration increasing pressure in >1 site of the foot	1
Peripheral Artery Disease (PAD)	<palpable pedal pulse (posterior tibial and dorsalis pedis arteries)	7
PREVIOUS DFU OR LEA	History of previous DFU or LEA	3
Multiple DFU	Presence of > DFU	4
Infection	Purulent discharge with 2 signs- warmth, erythema, lymphangitis,edema, Lymphadenopathy, pain)	4
Gangrene	Presence of necrosis(wet or dry)	10
Bone involvement	Bone exposure through visual inspection, touch with sterile probe, and/or bone involvement through X-ray.	7

2.AIMS AND OBJECTIVES

We Aim to classify severity of disease in patients with Diabetic Foot Ulcer using DIAFORA score. Our primary objective is to study patient outcomes at 90 days and predict lower extremity amputation. Our secondary objective is to estimate sensitivity and specificity of Diabetic Foot Risk Assessment Score for limb amputation in patients with diabetic foot ulcers.

3.MATERIALS AND METHODS

We conducted a prospective observational study on patients diagnosed with DFU in the Department of Internal Medicine and Department of Vascular Surgery in a tertiary hospital in Delhi. Figure 1 show the algorithm followed to study the risk of lower limb amputation using DIAFORA. We included 50 patients who were diagnosed with active Diabetic foot ulcer from September 2016 to July 2017. The sample size was calculated to test the sensitivity and specificity with the published values of 0.57 and 0.88 respectively.[11] Since the proposed study is time bound, therefore it was pursued as a pilot study with a sample size of 50 patients. Patients with non-healing wounds post lower limb amputations were excluded.

We collected data using a standardized predesigned study proforma by interviewing patients/patients attendants, during hospital visits. Using the monitored clinical parameters and investigations of patients, we classified them into mild, moderate and severe. The data was then entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. In normally distributed data comparison between groups were done with Independent T test or Mann-Whitney Test. Chi-Square test or Fisher exact test were used to establish correlation between qualitative variables. Receiver operating characteristic curve was used to find the cutoff point of score for predicting amputation. Univariate and multivariate logistic regression was used to assess significant risk factors of amputation.
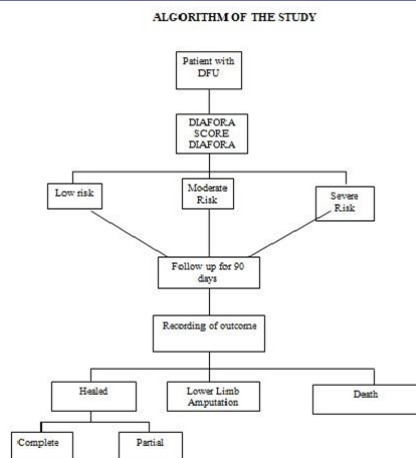
Figure 1: Algorithm to study risk of amputation in diabetic foot ulcer using DIAFORA

4.RESULTS

In this observational study conducted on 50 patients, the mean age of study subjects was 55.38 +/- 11.0 years with amputation observed more in males(47.62%) in comparison with the females. On classifying the patients, 30 patients (60%) were in the high risk group, 5 patients (10%) in medium risk group and 15 patients (30%) in low risk group.

Culture swabs from the ulcer sent for bacterial cultures growing organisms in our study showed that 44% patients had growth of gram negative bacteria, 30.5% had infection with gram positive bacteria and 25% had mixed growth.

70% of patients in the high risk group underwent amputation compared to none in the low risk group. However, 2 out of 5 patients in the medium risk group went for amputation. This data was statistically significant with a p value of 0.0001. 61.11% of patients (22/36) with infections, 69.70% (23/33) of patients with gangrene and 70% (21/30) patients with bone involvement were found to be independent risk factors for amputation with a significant p value of 0.001.

Univariate analysis showed gangrene and infection as independent risk factors for amputation (shown in table 2). Sensitivity and specificity of the score was 91.3% and 66.7% respectively with a negative LR ratio of 13% and a positive LR ratio of 70%. Positive predictive value was found to be 70% while negative predictive value was 90%. Receiver operator characteristics (ROC) curve analysis showed cut off value for high risk amputation to be 15 with sensitivity 100% and specificity 59.26% and Area under curve(AUC) of 0.81401.

Table 3: Showing various risk factors leading to amputation where parameters like infection, gangrene and total score are statistically significant.

Risk Factors	Amputation		Total	P value
	No	Yes		
Distal Peripheral neuropathy	26 (54.17%)	22 (45.83%)	48	1.000
Foot deformity	0(0%)	2 (100%)	2	0.207
PAD	16 (45.71%)	19 (54.29%)	35	0.121
Previous history of DFU/LEA	6 (37.50%)	10 (62.50%)	16	0.108
Multiple DFU	10 (47.62%)	11 (52.38%)	21	0.441
Infections	14 (38.89%)	22 (61.11%)	36	0.001
Gangrene	10 (30.30%)	23 (69.70%)	33	<.0001
Bone involvement	9 (30%)	21 (70%)	30	<.0001
Total	27 (54%)	23 (46%)	50	

5.DISCUSSIONS

Diabetic foot is defined as a foot affected by ulceration that is associated with neuropathy and/or peripheral arterial disease of the lower limb in a patient with diabetes.

After taking a brief history and doing focused examination, we applied

the DIAFORA score on all 50 patients with Diabetic foot ulcers included in our study. This score has 17% higher accuracy than other widely used scores[7].

Majority of patients with DFU in our study were males which is comparable with the study done by Rehman et al in 2005[14]and Chen H et al in 2006.[8]

Diabetic foot ulcers were more prevalent in the age group of 51-60 years. However, age was not a significant risk factor for amputation (p value-0.491) even in the univariate analysis.

This is comparable with a study performed earlier in Pima Indians.[9] Although, many studies showed association of age with neuropathic ulcers and peripheral vascular disease among diabetic individuals,[1,2] a study done in California showed incidence of amputation was higher in the age group of 65-74 years compared to individual above 75 years of age.[10]This observation of lower rate of amputation among the older diabetic patients in the above mentioned study can be due to relatively better health of the older population in that region or possibly due to reluctance to operate on older diabetic patients.

Prevalence of Distal Peripheral Neuropathy in our study was 96% compared to 60% in a Turkish study.[5]Contrary to our results which signify peripheral neuropathy as one of the important causes of foot ulceration, peripheral neuropathy had no independent effect on amputation as shown by statistical analysis (p value-1).

Peripheral artery disease as assessed by palpating pedal pulses and by Doppler studies was present in 35 patients, out of which 19 underwent amputation (54%) which was statistically insignificant (p value-0.121). This is in contrast with the available literature.[4] This difference in observation can be due to the smaller size of the study population or due to exclusion of Ankle Brachial Index for assessing Peripheral artery Disease in our study.

Infection is one of the major risk factors as 22 (61.11%) out of the total 36 patients who had infection in our study went for amputation with a significant p value of 0.0001. An Indonesian study showed 45.7% of patients with infections having undergone lower limb amputation.[12]

In our study, 69.70% of patients with gangrene (23/33 patients) had to undergo amputation with a p value of <0.0001 which is statistically significant. A study done by Pemayun et al also showed gangrene as one of the major risk factor for amputation.[12]

We assessed bone involvement by visual inspection, touch by sterile probe or by X Ray imaging of the affected limb. In our study, 21 out of 30 patients with bone involvement(70%) underwent amputation, which was significant(p<0.0001), similar to a single centre study done in Turkey which showed involvement of bone in diabetic foot as an independent risk factor for amputation.[5]

Coming to the final outcome of our study, Ulcer healed in 16 % patients and non-healing ulcers were observed in 34 patients out of which 23 patients (67.75%) underwent amputation which is statistically significant p value <.0001. Out of 50 patients in study, 23 patients (46%) had amputation and 27 patients (54%) did not undergo amputation. 21 out of 30 patients in the high risk group underwent amputation (70%) whereas none of the 15 subjects in the low risk group had to undergo amputation. However, 2 out of 5 patients in the medium risk group underwent an amputation. This data was statistically significant with a p value of 0.0001. There were no deaths reported in our study population. Sensitivity and specificity of the DIAFORAscore were 91.3% and 66.7% respectively, similar to the study done by Monteiro et al.[11]

The Receiver operator characteristic curve obtained from our study data showed a cut off of 15 which is different from the earlier published data of 18 which can be attributed to the study being conducted in a population where there is higher prevalence of Diabetes Mellitus.[11]

6.CONCLUSION

Our study concluded the significant role independent risk factors like infection, bone involvement and gangrene play in amputation. 70% of the patients in the High risk group of our study underwent amputation

whereas no amputation was observed in our low risk group population. According to our study, the DIAFORA score has a sensitivity of 91.3% and specificity of 66.7%. Therefore, we recommend the use of DIAFORA score for DFU classification in routine clinical practice to predict lower limb amputation. Educating patients about regular self-foot care and periodic foot examination is an unparalleled practice. Large scale studies with longer follow up needs to be done to know the efficacy of this Diabetic Foot Ulcer classification better. In centers with no provision of MAT Scan for foot deformity, obvious deformity of foot can be looked for.

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